

REMARKS

Claims 1 and 5-19 are pending and have been examined on the merits. Claims 17 and 18 are amended hereinabove and claim 16 is cancelled. No new matter has been added.

In the Office Action, the claims are rejected as follows:

1. Claims 16-18 remains rejected to under 37 C.F.R. § 112, ¶ 2 for allegedly being indefinite; and
2. Claims 1 and 5-19 remains rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Bromberg et al. (U.S. Patent Application Publication No. 20030152623, hereinafter “Bromberg”) in view of Blum et al. (U.S. Patent No. 6,294,591, hereinafter “Blum”), Giammona et al. (Biochimica et Biophysica Acta, 1999, hereinafter “Giammona”) and Cavazza (U.S. Patent No. 6,013,670, hereinafter “Cavazza”).

Applicants respectfully traverse.

Rejection under 37 C.F.R. § 112, ¶ 2

Claim 16 is cancelled rendering its rejection moot. In addition claims 17 and 18 are amended to correct their dependency. Accordingly, Applicants respectfully request that in light of the claim amendment the rejection under 37 C.F.R. § 112, ¶ 2 be reconsidered and withdrawn.

Rejection under 37 C.F.R. § 103(a)

Applicants wish to incorporate herein by reference the previous responses and wish to add the following additional remarks.

As previously submitted, the presently claimed invention is directed to anionic hydrogel matrixes obtained by chemical reticulation by means of irradiation of copolymers containing photoreticulable groups, wherein the photoreticulable groups are derived from the insertion of

glycidyl methacrylate (GMA) and methacrylic anhydride (MA) in the side chain of PHEA in the presence of acid comonomers (*e.g.*, page 3, lines 1-14).

As also previously submitted Bromberg does not provide for the specific polyaspartamide derivatized polymers presently claimed. On the contrary, Bromberg discloses a plethora of suitable polymers (*e.g.*, paragraphs [0087]-[0115] for a total of 11 pages). Thus, one skilled in the art would find no motivation to choose a poly-L-aspartic acid among the laundry list of components disclosed in Bromberg and modify it as presently disclosed without the help of the impermissible hindsight. *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007) (“A claimed compound would not have been obvious where it was not obvious to try to obtain it from a broad range of compounds, any one of which could have been selected as the lead compound for further investigation,and there was not reasonable expectation of success”).

As also previously submitted, Blum only teaches that it is possible to form polymers with reactive side groups but it is completely silent with regard of PHEA. Further, Blum is not analogous to the field of Applicants’ endeavor (MPEP § 2141.01(a)). *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337 (Fed. Cir. 2008). *Agrizap* stands for the proposition that analogous art is not limited to references in the field of endeavor of the invention, but also includes references that would have been recognized by those of ordinary skill in the art as useful for Applicants’ purpose. However, these are not the fact of the case. Blum relates to polymers known and used to produce radiation-curable coatings, paints, adhesives or impregnating compositions (*e.g.*, col. 1, lines 9-11). These are not purposes useful for Applicants’ invention.

Moreover, Applicants respectfully disagree with the Examiner’s statement on page 12 of the Final Office Action.

As an initial matter, the Examiner's citation of Blum on page 12 of the Final Office Action "the selection of monomers for combination is made in accordance with principles familiar to the skilled workers such that they satisfy the requirements of the envisage application. These requirements may differ greatly;" (*e.g.*, col. 3, lines 36-39) is taken out of context and is incomplete.

It necessary follows that also the Examiner's conclusion on page 12 of the Final Office Action "a person of ordinary skill in the pharmaceutical arts would thus readily recognize and be able to take advantage of the relevant teachings that Blum affords to the pharmaceutical arts" is erroneous.

On col. 3, lines 39-47, Blum continues the Examiner's citation disclosing that "These requirements may differ greatly; for example, transparent automotive topcoats for metallic finishes are required to have very high resistance to yellowness and weathering, high scratch resistance and good gloss retention coupled with high hardness."

Accordingly, Applicants assert that unlike the Examiner's asserted conclusions, Blum does not afford relevant teachings to the pharmaceutical arts. Nothing in Blum hints to the pharmaceutical arts, and therefore, unlike in *Agrizap*, one skill in the art would not have recognized Blum as been useful for Applicants' purposes.

Therefore, one skilled in the art of making drugs would not look at the teachings of Blum, who are limited only to the field of making paintings, to learn how to prepare a drug formulation. Thus, Blum should not be used as a reference to sustain an alleged obviousness rejection of Applicants' claims.

Finally, Applicants previously submitted that Giammona is completely silent with regard to PHEA derivatisable with GMA and MA. In the Final Office Action, the Examiner responded

to Applicants' arguments by saying that "it was already established and disclosed at the time of the present application that PHEA could be photo-crosslinked by insertion of GMA into the side chain and that one skilled in the art would have found obvious to insert MA starting from the teaching of Blum (*e.g.*, Final Office Action, page 13). Applicants respectfully disagree with these conclusions.

First, obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so. *In re Kahn*, 441, F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006). As set forth above, Blum provides no motivation to one skilled in the art to insert MA into PHEA photo-crosslinked by insertion of GMA into the side chains. On the contrary, Blum is not analogous to the field of Applicants' invention and does not provide any useful teaching for the person of skill in the pharmaceutical art.

Second, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007). The simple reason that Blum and Giammona can be combined is not enough to render obvious the claimed subject matter because one of ordinary skill in the art would not even have considered Blum as a relevant reference to be combined with Giammona.

Moreover, a statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill in the art at the time the claimed invention was made" because the references relied upon teach all aspects of the claimed invention were individually known in the art, is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*,

28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). Thus, the Examiner's statement that it was established and disclosed at the time of the present application that PHEA could be photo-crosslinked by insertion of GMA into the side chain and thus, any person of ordinary skill in the art would find it obvious from the disclosure of Blum to insert MA as well, is not enough to establish a *prima facie* case of obviousness. No objective reasons or motivations have been provided to explain why such teachings should be combined.

Finally, Cavazza is irrelevant with regard to the presently claimed anionic hydrogel matrix composition as recited in claims 1, 5-14. Cavazza only provides for the treatment of chronic inflammatory bowel diseases with lower alkanoyl L-carnitines (*e.g.*, col. 1, lines 6-10). Thus, it cannot render obvious the subject matter of claims 1, 5-14.

Further, as Bromberg, combined with Blum and Giammona would not have rendered obvious the claimed subject matter for the reason set forth above, it is respectfully submitted that they would not have rendered obvious the subject matter of claims 15 and 17-19 as well. Thus, Cavazza, which does not cure the deficiencies of any of the cited references because it suffers from the same defects, would also not have rendered obvious the subject matter of claims 15 and 17-19.

Accordingly, Applicants respectfully request that the rejection of claims 1 and 5-19 under 35 U.S.C. § 103(a) for allegedly being obvious over the combination of the cited references be reconsidered and withdrawn.

Conclusions

This response is being filed within shortened statutory period for response. Thus, no further fees are believed to be required. If, on the other hand, it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby

authorized to debit or credit such sum to Deposit Account No. 02-2275.

Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,
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Dated: November 4, 2010

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